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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,329	10/27/2000	Eiichi Iishi	1422-449P	8402
7590 07/22/2005 Birch Stewart Kolasch & Birch LLP P O Box 747 Falls Church, VA 22040-0747			EXAMINER HABTE, KAHSAY	
			ART UNIT 1624	PAPER NUMBER

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/697,329	IISHI ET AL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kahsay Habte, Ph. D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7 and 12-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 and 12-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. Claims 7 and 12-17 are pending.
2. In view of the appeal brief filed on June 6, 2005, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below (see 4-5).

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaspersen *et al.* {Journal of Label. comp. and Radiopharm., 27, No. 9, 1055

(1989)} in view of Khankari et al. {Thermochemica Acta 248 (1995) 61-79}. Kaspersen et al. teaches the multi-step synthesis of Org-3770 (mirtazapine) on page 1058 (Fig.4). On page 1066, Kaspersen et al. teaches the synthesis of mirtazapine and the crystallization of the mirtazapine (compound 1c) from the crude product using methanol/water solvent mixture to achieve colorless crystals. The only difference between applicant's mirtazapine hydrate and Kaspersen's Org-3770 hydrate is that Kaspersen's hydrate is <sup>13</sup>carbon labeled, but the instantly claimed product requires that the mirtazapine be unlabeled. The structure of Kaspersen's mirtazapine and the structure of applicants unlabeled mirtazapine are extremely closely related. Just as the labeled compound clearly suggests the unlabelled so do the labeled hydrate clearly suggest the unlabelled hydrate. This is particularly true since the labeled compound was prepared in order to study what the known unlabelled compound does in the body. As shown in Khanakari et al., hydration alters pharmaceutically important properties such as solubility and the physical and chemical stability of pharmaceutical solids that contributes in the modification of bioavailability and product performance (see page 64). It is obvious to one skilled in the art to modify the labeled Kaspersen's mirtazapine hydrate to a hydrated unlabeled mirtazapine compound, since hydration alters the physical chemical or biological performance of a pharmaceutical drug (e.g. bioavailability, solubility, stability) and the fact that hydrates are a conventional form of making a pharmaceutical composition as shown in Khanakari et al. (see page 77, last paragraph). Thus, the prior art teaching that mirtazapine forms a hydrate in the labeled form would suggest that mirtazapine forms a hydrate in the unlabelled form, since one

expects that labeled and unlabeled to have the same physical properties. One is motivated to prepare this unlabeled hydrates because (1) drugs are normally administered in their unlabelled form (which is the form that mirtazapine is commercially available in) and (2) the hydrate is a standard pharmaceutical form as is shown by the secondary reference. Thus, the teaching that mirtazapine (albeit labeled) forms a hydrate would provide the motivation for preparing the unlabeled mirtazapine in a hydrate form for pharmaceutical use.

### ***Response to arguments***

Applicants arguments filed 06/06/2005 have been fully considered but they are not persuasive. Applicants argue:

"When a rejection is based on 35USC §103, what is in issue in such a rejection is 'the invention as a whole,' not just a few features of the claimed invention. Under 35 U.S.C. §103, '[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.' The determination under §103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. See In re O'Farrell, 853 F.2d 894, 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). In determining obviousness, the invention must be considered as a whole and the claims must be considers in their entirety. See

Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721, F.2d 1563, 1567, 220 USPQ 97, 101 (Fed. Cir. 1983)."

The examiner disagrees with applicant's argument above, since the obviousness rejection was based on the invention as a whole, but not just a few features of the claimed invention. The claimed invention is drawn to a hydrated unlabeled mirtazapine crystals and use of said hydrated unlabeled mirtazapine crystals for the treatment of depression. The obviousness rejection is based on Kaspersen's in view of Khanakari et al. that teaches the advantages of hydration in pharmaceutical compositions. Note that Kaspersen labeled compounds were prepared for metabolic studies in animal and man for the determination of the bioavailability. According to page 1055, Kaspersen's hydrated mirtazapine are tested as a potential antidepressant as the utility of the claimed invention.

Applicants also argue:

" In rejecting claims under 35 USC 103, it is incumbent on the examiner to establish a factual basis to support the legal conclusion of obviousness. See, In re Fine, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the examiner is expected to make the factual determinations set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), and to provide a reason why one of ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reasoning must stem from some teaching, suggestion

or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. Uniroyal Inc. v. F-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988), cert. denied, 488 U.S. 825 (1988); Ashland Oil. Inc. v. Delta Resins & Refractories. Inc., 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986); ACS Hospital Systems. Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 22 1 USPQ 929, 933 (Fed. Cir. 1984). These showings by the examiner are an essential part of complying with the burden of presenting a prima facie case of obviousness. Note, In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The mere fact that the prior art may be modified in the manner suggested by the examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. In re Fritch, 972 F. 2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992)."

In regard to the argument "that the prior art suggest the desirability of the modification", the examiner disagrees. This is not a device case. Kaspersen does not have to suggest any modifications or suggest the labeled compound as a hydrate. . The fact that antidepressants administered clinically are always non-labeled could provide all the motivation. There is no requirement for the obviousness rejection that the labeled compound as a hydrate. The compound is asserted to be inherently a hydrate because it is made via a method which applicants use to prepare hydrate. According to MPEP 2112.01:

*Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). [underscoring added]*

Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Applicants also argue: "Kaspersen et al. would have at their disposal, the data relating to the anhydrous mirtazapine compounds as described in the reference cited in foot note "1" in the Introduction section. It is reasonable to conclude that Kaspersen et al. would be able to discern whether a hydrate was formed in their workup using TLC, HPLC or GC methods based on comparing their retention times to the retention times described in the reference cited in foot note "1" in the introduction section". The examiner disagrees with this argument, since this is just a mere speculation. Applicants are speculating that the antidepressant drug in said foot note "1" is anhydrous mirtazapine. Reference is silent on whether it is anhydrous. There is no indication in Kaspersen et al. that this antidepressant drug is in fact anhydrous. Thus,

the argument that the retention times described in said footnote "1" {Drugs of the Future 10 965 (1985)} can be compared to that of Kaspersen's is irrelevant. In fact, said article has no information about retention time, melting point, NMR, or IR data that can be compared to that of Kaspersen. The paper is not concerned with this but rather with biological properties.

Applicants also argue "With respect to the IR technique for measuring hydrates, Fig. 1 of the present application shows how clearly the O-H stretching vibration shows at  $\sim 3000\text{ cm}^{-1}$ . It is reasonable to presume that for accuracy sake, Kaspersen et al. would report this peak associated with water if Kaspersen et al. in fact made the mirtazapine hydrate asserted by the Examiner". The examiner disagrees with applicants. The IR peaks reported by Kaspersen et al. does not necessarily show a complete spectrum of the labeled mirtazapine compound. Thus, it is incorrect to use the only 4 peaks reported by Kaspersen as the only peaks for the molecule. It is presumed that these peaks are the only important ones for the sake of the report, but not the "only" peaks for the molecule. In fact, in many IR data reports only important peaks are reported and usually peaks from water or other weak peaks are ignored. The peaks are not usually reported because they are very broad or they are not important because they are not part of molecule. Thus, applicant's argument that the IR-spectrum described by Kaspersen et al. do not include a peak around  $3000\text{ cm}^{-1}$  is not persuasive. Additionally, the examiner is providing six US Patents (5,284,857; 5,401,753; 5,397,790; 5,583,149; 4,524,146 and 5,468,768) as an evidence to rebut applicant's argument. In said US Patents, that disclose different type of hydrates the

water peak around  $3000\text{ cm}^{-1}$  was not reported when the IR data was taken using KBr that is the same as Kaspersen. Specifically, in US Patents 5,583,149 and 5,468,768 (column 17, lines 30-38 and column 17, lines 16-21) the IR(KBr) peaks for the hemifumarate hydrate compound were reported as  $1660$ ,  $1575$  and  $1375\text{ cm}^{-1}$ . In US Patent 5,397,790 (column 14, EXAMPLE 23), the IR(KBr) peaks for the hemihydrate product were reported as  $1790$ ,  $1670$  and  $1600\text{ cm}^{-1}$ . Similarly, in US Patent 5,401,753 (column 12, EXAMPLE 18) for one-quarter hydrate of the title compound ( $n = 1/4$ ) the IR(KBr) peaks were reported as  $1780$ ,  $1665$  and  $1610\text{ cm}^{-1}$ . A hydrate product of the pyrazolo[4,3-c]quinoline derivative in US Patent 4,524,146 (column 9, EXAMPLE 2), the IR(KBr) peaks were also reported as  $800$ ,  $829$ ,  $870$  and  $880\text{ cm}^{-1}$ . A quarter hydrate product ( $n = 1/4$ ) in US Patent 5,284,857 (column 30, EXAMPLE 96) were also reported with an IR(KBr) peaks at  $1667$ ,  $1658$ ,  $1638$ ,  $1613$ ,  $1600$ ,  $1568$  and  $1476\text{ cm}^{-1}$ . Note that the hydrates of said US Patents do not contain any IR(KBr) peaks at around  $3000\text{ cm}^{-1}$ . It may be conventional to ignore peaks not part of the base molecule, or the water peak may have been broadened to the point where it was not seen, especially if the water amount was small.

In regard to the NMR data, applicants argue that Khanakari et al. show how readily discernible the dihydrate form of carbamazepine is using  $^{13}\text{C}$  NMR....Kaspersen et al. would identify and report that the labeled compound [10- $^{14}\text{C}$ ]-Org 3770 is a hydrate in the  $^{13}\text{C}$  NMR of Fig. 9 on page 1061, if Kaspersen et al. in fact made the mirtazapine hydrate asserted by the Examiner". The examiner again disagrees with applicants. The hydrated mirtazapine crystals and Khanakari's carbamazepine are two

different chemical compounds. Khanakari's carbamazepine compound is a dihydrate compound that has a lot of water in it. One skilled in the art expects that this dihydrate peak to show up in the  $^{13}\text{C}$  NMR, but for Kaspersen the water content is very little (i.e.  $1/n$ , where  $n = 1-5$ ). The presence or absence of water peaks in  $^{13}\text{C}$  NMR peaks alone cannot be used for identifying a compound as a hydrate or unhydrate, unless otherwise other measurements are performed to confirm. A water peak in  $^{13}\text{C}$  NMR could mean not necessarily the presence of a hydrated compound.

Both applicants and Kaspersen use an extremely similar method, thus, it is presumed that the same hydrate product is formed from virtually the same crystallization method. Kaspersen *et al.* on page 1066 teaches the synthesis of mirtazapine and the crystallization of the mirtazapine (compound 1c) from the crude product using charcoal, methanol/water solvent mixture to achieve colorless crystals. Applicants on page 6 (lines 5-6) also discloses mixed solvents such as methanol/water, plus charcoal to make crystals of a mirtazapine hydrates. The only difference between applicant's mirtazapine and Kaspersen's Org-3770 is that Kaspersen's compound 1c is  $^{13}\text{C}$  carbon labeled, but the instantly claimed product requires that the mirtazapine be unlabeled. One skilled in the art would presume that labeled and unlabelled would crystallize in the same way.

In regard to applicant's argument that the processes of making hydrates (see Inventive Examples 1, 6, 8 and 11) are different from that of Kaspersen's, the examiner disagrees with applicants. This is a speculation. Whether a thin stream of water is

added to the solution or the water is part of the water/methanol mixture in crystallizing the mirtazapine, it makes no difference in making hydrates. Applicants only have to replicate Kaspersen (with or without the label; either is acceptable) and clearly on record show that the water from the crystallization process is not present.

Applicants and Kaspersen use almost the same method to prepare crystal of mirtazapines, thus, it is obvious that these two have the same characteristics (i.e. hydrates). The examiner has established reasonable grounds that Kaspersen's mirtazapine product as a hydrate (see above). It is up to applicants to replicate Kaspersen and show that Kaspersen product that includes water is not a solvate. Water present in a crystalline product is normally presumed to be a hydrate. Applicants have made the same presumption here.

Since the hydrate of the labeled compounds could just as well be important intermediates for preparing anhydrous labeled mirtazapine crystals and the fact that the hydrates are the conventional way of making pharmaceutical formulation as shown above, the obviousness rejection is proper. Note that obviousness can be for any purpose. Here, since unlabeled mirtazapine is known pharmaceutical, its unlabeled hydrate can be obvious for pharmaceutical purposes, even if it is not obvious for metabolic studies.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1624

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-17 are rejected under 35 U.S.C. 102(b) as anticipated by Van den Oetelaar et al. (EP 0431 663). Van den Oetelaar et al. teaches the pharmaceutical formulation of mirtazapine compounds on column 2 (lines 20-34) for the treatment of depression. Water solutions are one of the known formulations for pharmaceutical composition. Applicants claim a method for treating a human suffering from depression, comprising administering a pharmaceutically acceptable composition prepared from an effective amount of mirtazapine crystals having a hygroscopic degree of not more than 0.6% by weight when the crystals are stored in the air having a relative humidity of 75% at 25 degree celsius under atmospheric pressure for 500 hours, is the same as Van den Oetelaar et al. Since a mirtazapine crystal in aqueous solution is a pharmaceutical composition and would no longer have this property. The same material is obtained. That is, once the material is dissolved in water, it is the same solution regardless of whether the original form was hydrated or not.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 12-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a crystal of an unlabeled mirtazapine  $n = 3$ ,

does not reasonably provide enablement for a crystal of an unlabeled mirtazapine  $n = 1-2$  and  $4-5$ . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The specification does not teach  $n = 1-2, 4$  and  $5$ . The formula (I) species that  $n$  is an integer of  $1$  to  $5$ . Claim 7 therefore covers five embodiments of crystals of mirtazapine hydrate and these are specifically crystals having a ratio of mirtazapine molecules to hydrate molecules of  $1:1, 1:2, 1:3, 1:4$  and  $1:5$ . According to the specification (Example 1), the water content reported is  $2.3\%$ . According the Communication of a Notice of Opposition to EP 1225174 by Teva Pharmaceutical Industries (pages 3-4, submitted on 3/4/2005) that is part of the disclosure in this case, the water content  $2.3\%$  corresponds to  $n = 2.88$  (non-integer). In this communication, there is an Affidavit by Professor Micheal B. Hurthouse as evidence that it is physically impossible to form the monohydrate crystal ( $n=1$ ). Thus, claim 7 covers an embodiment, which does not exist. It is therefore no surprising that the instant case does not provide an enabling disclosure for  $n=1$ . Since there is no description how to prepare a specific hydrates falling within the scope of claim 7 (i.e.  $n=1-2$  and  $4-5$ ), the enablement rejection is proper.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 17, the phrase "represented by the formula I" is not clear. Is it referring to the mirtazapine crystal as final product and crystals of a mirtazapine hydrate represented by the formula I as starting material, or is it referring to mirtazapine hydrate represented by the formula as a final product and the mirtazapine crystal as a starting material?

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

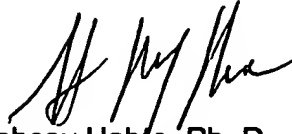
Application/Control Number: 09/697,329

Page 15

Art Unit: 1624

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kahsay Habte', is positioned above the printed name.

Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624

KH  
July 19, 2005